UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/526,125 | 06/15/2006 | Mariagrazia Pizza | PP019813.0003 | 2934 |

27476 7590 12/29/2006

NOVARTIS VACCINES AND DIAGNOSTICS INC.
CORPORATE INTELLECTUAL PROPERTY R338
P.O. BOX 8097
Emeryville, CA 94662-8097

| EXAMINER | |
|---|---|
| RAGHU, GANAPATHIRAM | |
| ART UNIT | PAPER NUMBER |
| 1652 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 31 DAYS | 12/29/2006 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/526,125 | PIZZA ET AL. | |
| | Examiner | Art Unit | |
| | Ganapathirama Raghu | 1652 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 June 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-15 are pending in this application.

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I: Claims 1-9 and 11, in part drawn to a mutant *Neisseria meningitides* ADP-ribosylating enzyme or to a fragment thereof and to an immunogenic composition, wherein said mutant enzyme comprises the amino acid sequence of SEQ ID NO: 2.

Group II: Claims 1-9 and 11, in part drawn to a mutant *Neisseria meningitides* ADP-ribosylating enzyme or to a fragment thereof and to an immunogenic composition, wherein said mutant enzyme comprises the amino acid sequence of SEQ ID NO: 3.

Group III: Claims 1-9 and 11, in part drawn to a mutant *Neisseria meningitides* ADP-ribosylating enzyme or to a fragment thereof and to an immunogenic composition, wherein said mutant enzyme comprises the amino acid sequence of SEQ ID NO: 4.

Groups IV-VI: Claim 10, drawn to use of elected mutant protein in the manufacture of a medicament for raising an immune response in an animal, wherein Group IV corresponds to Group I mutant protein ... and Group XII corresponds to Group III mutant protein.

Groups VII-IX: Claim 12, drawn to an antibody that binds to the elected mutant protein, wherein Group XIII corresponds to antibody that binds to Group I mutant protein ... and Group XV corresponds to antibody that binds to Group III mutant protein.

Groups X-XII: Claim 13, drawn to a nucleic acid encoding the elected mutant protein, wherein Group XVI corresponds to nucleic acid encoding Group I mutant protein ... and Group XVIII corresponds to nucleic acid encoding Group III mutant protein.

Groups XIII-XXI: Claim 14, drawn to a method of treating a patient, comprising administering a therapeutically effective amount of elected mutant proteins of Groups I-III or the antibodies of Groups VII-IX or the nucleic acid of Groups X-XII, wherein Group XIII corresponds to administering Group I mutant protein ... and Group XV corresponds to administering Group III mutant protein; Group XVI corresponds to administering antibody of Group VII ... and Group XVIII corresponds to administering antibody of Group IX; Group XIX corresponds to administering the nucleic acid of Group X ... and Group XXI corresponds to administering the nucleic acid of Group XII.

Group XXII: Claim 15, drawn to a process of diminishing the ADP-ribosylating enzymatic activity of a *Neisseria meningitides* ADP-ribosyltransferase protein.

The inventions listed as Groups I-XXII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following categories:

1) A product and a process specially adapted for the manufacture of said product or

2) A product and process of use of said product; or

3) A product, a process specially adapted for the manufacture of said product and a use of said product; or

4) A process and an apparatus or means specifically adapted for carrying out the said process; or

5) A product, a process specially adapted for the manufacture of said product and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(c) states: If an application contains more or less than one of the combination of categories of in an invention set forth in paragraph (b) of this section, unity of invention might not be present.

In addition, the PCT does not provide for multiple products or methods within single application, therefore, unity of invention is lacking with regard to Groups I-XXII; see 37 CFR 1.475. 37 CFR 1.475 (d) also states: If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) 1.47(c).

37 CFR 1.475(e) further states; the determination whether a group of invention is so linked as to form a single inventive concept shall be without regard to whether the inventions are claimed in separate claims or as alternative within a single claim.

In the instant application the products of Groups I-III, VII-IX and X-XIII differ substantially from one another to the extent that they have a different structure and function. The polypeptides of Groups I-III, antibodies of Groups VII-IX and nucleic acids of Groups X-XIII are structurally and functionally different. For example the antibodies of Groups VII-IX bind to different polypeptides with differing binding affinities and are structurally different from the polypeptides of Groups I-III. The above products can be used exclusive of each other such that they do not share unity of invention under 37 CFR 1.475.

Furthermore, the inventions listed as Groups I-XXII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical features linking the inventions of Groups I-XXII appears to be that they all relate to an isolated a mutant *Neisseria meningitides* ADP-ribosylating enzyme and use of the same as an immunogenic composition. However, Domenighini et al., (Mol. Microbiol., 1994,

Vol. 14 (1): 41-50) disclose the analysis of the three-dimensional structure of ADP-ribosylating toxins and the determination NAD-site involved in the toxicity and teaches that the tertiary folding of the structure is strictly conserved despite the differences in amino acid sequence from enzymes of different origin. Furthermore said reference discloses the catalytic property of the enzyme is determined by two spatially conserved amino acid residues, especially glutamic acid and histidine depending on the origin of the enzyme/toxin (Abstract section and entire document).

Therefore the technical features linking the inventions of Groups I-XXII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, Groups I-XXII are not so linked by the same or a corresponding special technical feature as to form a single inventive concept.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Rejoinder of restricted inventions***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitation of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. 821.04. Process claims that depend from or otherwise include all the limitation of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised

that process claims should be amended during prosecution either to maintain dependency on the product claims or otherwise include the limitation of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached on 8 am - 4.30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ganapathirama Raghu, Ph.D.
Patent Examiner
Art Unit 1652
Dec. 18, 2006.

SHERIDAN SWOPE, PH.D.
PRIMARY EXAMINER
AU 1652